

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 4239-66642	<b>FOR FURTHER ACTION</b>	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US03/31321	International filing date ( <i>day/month/year</i> ) 01 October 2003 (01.10.2003)	(Earliest) Priority Date ( <i>day/month/year</i> ) 02 October 2002 (02.10.2002)
Applicant THE GOV. OF THE U.S.A. AS REPRESENTED BY THE SECRE		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (See Box II).

4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. \_\_\_\_\_



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/31321

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: claims 1-14 (SEQ ID NO. 2 and 6) and claims 23-36, 40-54 (SEQ ID NO. 6)
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐  
☐

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/31321

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/00; C07K 7/00

US CL : 530/324; 514/12

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 530/324; 514/12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2003/0008284 A1 (KENNEDY et al) 09 January 2003 (01.09.03), see [0215] and [0204]	1-2, 11-14 ----- 23-26, 30-32
X	Database Genseq, Alexandria, VA, AN AAM48961, KENNEDY et al, 'Detecting a cancerous colon cell, useful for diagnosing colon cancer and for rational drug and therapy design, comprises detecting at least one differentially expressed gene product' WO 01/196523 20 December 2001 (20.12.01).	1-2, 11-14
X	Database Genseq, Alexandria, VA, AN AAB43305, SHIMKETS et al 'Novel nucleic acids and peptides derived from open reading frame X, useful for treating e. g. cancers, proliferative disorders, neurodegenerative disorders and cardiovascular disease', WO 00/05873 05 October 2000 (05.10.00).	1-2, 11-14
X	Database Genseq, Alexandria, VA, AN AAB86210, 'new nucleic acid encoding interactors of Fanconi anemia protein, useful for diagnosis, treatment and prevention of e. g. DNA-repair defects or cell-cycle disorders', WO 01/140461 07 June 2001 (06.07.01).	1-2, 11-14

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

29 December 2004 (29.12.2004)

Date of mailing of the international search report

25 JAN 2005

Name and mailing address of the ISA/US

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# INTERNATIONAL SEARCH REPORT

PCT/US03/31321

## BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-14, drawn to nucleostemin polypeptide.

Group II, claim(s) 15-22, drawn to isolated polynucleotides. Vectors and host cells.

Group III, claim(s) 23-36, 40-54 drawn to method for inducing differentiation or inhibiting proliferation of a cells by altering the level of nucleostemin.

Group IV, claim(s) 37-39, drawn to method of screening for agents that affect differentiation or proliferation of a cell.

Group V, claim(s) 55-62, drawn to method for inducing differentiation, inducing senescence or inhibiting proliferation of a cell.

Group VI, claim(s) 63, drawn to antibody directed against the polypeptide of claim 1.

In addition, with Group I, applicant will have SEQ ID NO. 2 examined without paying additional fees.

In addition, if applicant pays for Group II, they will get Group II as it reads on SEQ ID NO. 1. If applicant wants any more sequences, they need to pay additional fees.

In addition, if applicant pays for Group III, they will get Group III as it reads on SEQ ID NO. 6. If applicant wants any more sequences, they need to pay additional fees.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the products of Group I-II and VI differ structurally and functionally and this lack the same or corresponding special technical feature. Each of the methods of Group III-V require the use of different products. The product required in Group III is a polypeptide. The product in Group IV is any agent. The product in Group V is a polypeptide different from that in Group III.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure, which is a significant structural element. Although SEQ ID No. 1 and 3 share a common structure of a single nucleic acid, the compounds are not regarded as being of similar nature because the shared common structure is not a significant structural element. A common structure of a single nucleic acid is not a significant structural element because the nucleic acid is found in every nucleic acid sequence.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure, which is a significant structural element. Although SEQ ID No. 2 and 4 and 6 and 8 and 10 share a common structure of a single amino acid, the compounds are not regarded as being of similar nature because the shared common structure is not a significant structural element. A common structure of a single amino acid is not a significant structural element because the amino acid is found in every amino acid sequence.